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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER

DATE MAILED: 17

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/572,027	Debonte et al.
Examiner	**Group Art Unit**
Gary Benzion, Ph.D.	1649

X Responsive to communication(s) filed on *24 Apr 1998*.

X This action is **FINAL.**

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *1-3, 5-10, 27-29, 31-35, 37-46, and 55-66* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) *1-3, 5-10, 27-29, 31-35, 37-46, and 55-66* is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

Status of the Application

Effective February 7, 1998, the Group and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1649.

The claims

Claims 1, 5-7, 10, 27, 32, 35, 40 and 44-46 are newly amended. Claim 66 is newly added. Claims 4, 11-26, 30 and 36 are newly canceled. Claims 1-3, 5-10, 27-29, 31-35, 37-46, 55-65 and 66 are pending.

Detailed Action

Newly submitted claim 66, and amended claim 10 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: They present for further search and consideration the motif Tyr-Leu-Asn-Asn-Pro and the mutation of this motif Tyr-His-Asn-Asn-Pro which forms a genus of original claim 10, but was not represented by any originally claimed species. And while it is well taken that a species may anticipate and make obvious a genus the converse is not always true. While it is noted that claim 10 originally presented the motif Lys-Tyr-His-Asn-Asn-Pro it is unclear if the modification of that motif by the removal of the first residue would affect the product of the invention.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 10 and 66 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP 821.03.

Claim 31-33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-33 depend from canceled claim 30 and as such fail particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5-7, 27, 32, 35, 40 and 44-46, newly amended, are rejected and claims 2-3, 8-9, 28-29, 31, 34-35, 37-39, 41-43 and 55-65 remain rejected under 35 U.S.C.§ 112, second paragraph, for the reasons of record as applied to unamended claims 1-46 and 55-65, as set forth at pages 4-5 of the previous Office Action, pertinent positions as listed below.

The prior Office Action stated:

> The specification clearly disclose that the mutation enabled are those that occur in the amino acid (aa) motif *His Xaa Xaa Xaa His*. To the person having skill in the art a mutation that affects an *aa* sequence need not affect the *aa* function, such as conservative substitutions or point mutation, and while mutations which affect oleic acid levels could be due to modification in the steady state activity of the enzyme encoded, such as down or up regulation, the specification clearly teaches the limitation of mutations to include only those which make the enzyme non-functional. Attention is directed to page 18, where applicants state:
>
> > Mutations in any of the regions of the Tables 1-6 are specifically included within the scope if the invention, provided that such mutation (or mutations) renders the resulting desaturase gene product non-functional, as discussed herein above.
>
> Finally, all mutations must be defined in terms of what is considered to be the "wild type" of a gene, and in this regard, the specification teaches modifications in the motif "His Xaa Xaa Xaa His" as exemplified by a non-conservative substitution from HECGH to HKCGH (pages 14/15). These modification apparently result in the absence of function of the gene product (page 18) and do not encompass mutations which result in up or down regulation. Accordingly, the claims fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants argue that the specification at page 12, lines 1-18 describe the mutations which render the gene product non-functional, as inferred from a decreased level of reaction product and an increased level of substrate. Applicants' arguments have been carefully considered and are not deemed persuasive.

It is improper to read unwritten limitations from the specification into pending claims contrary to the plain words of those claims. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As demonstrated in the previous Office Action and herein below, the plain meaning of mutation is not limited to the teaching in the specification. Amending the claims to place the specific mutations in the claimed motif in the specific aa location would be seen to obviate this rejection.

Claim 1-3, 5-10, 27-29, 31-34 and 66 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation of claim 1, and those related claims, are directed to an isolated nucleic acid fragment comprising a sequence of "at least about 20 nucleotides" is not linked to the further limitation of "in a region of said desaturase gene encoding a His-Xaa-Xaa-Xaa-His amino acid motif as the later limitation refers to a gene while the former refer to a fragment. Thus the 20 nucleotide need to which the claims are drawn need not comprise the motif. Accordingly the claims fail to clearly set forth the metes and bounds of the invention taught in the specification.

Claims 1 and 5, newly amended, are rejected and claims 2-4 and 8-9 remain rejected under 35 U.S.C.§ 102(b) as being clearly anticipated by Jonathan Edward Lightner[1] et al., for the reasons of record as previously applied to unamended claims 1-5, 8-9, 11-12, 14-15 and 19-21 as set forth at pages 7-8 of the previous Office Action.

Applicants argue that Lightner et al. do not describe a mutation in a region encoding a His-Xaa-Xaa-Xaa-His[2] motif in a Δ-12 desaturase and instead state that the desaturase in this publication is that of a wild-type Δ-12 desaturase. Applicants' arguments have been carefully considered and are not deemed persuasive.

The prior art reference clearly disclose the claimed motif as residing in an isolated Δ-12 desaturase. There is no requirement in the claims[3] the "mutation" alter the fatty acid composition in any particular way from any specific base sequence. In this regard Official Notice is taken that the concept of mutation included changes in which the DNA sequence is changed but the amino acid sequence is unaltered or altered in a conservative manner. In Watson et al. The Molecular Biology of the Gene[4], at page 438, this concept is clearly stated:

> ... mutations in the first position of a code word will usually give a similar (if not the same) amino acid. Furthermore code words with pyrimidines in the second position specify mostly

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1 Lightner et al. was referenced as Edwards et al. in error. As this distinction was recognized by applicants the error is considered harmless.

[2] The motif *HRRHHH* was correctly understood by applicant to in fact refer to *HRRHH*.

[3] Claim 1 as amended, for example, requires a least one mutation in the designated *His-Xaa-Xaa-Xaa-His* motif.

[4] 4th edition, The Benjamin/Cummings Publishing Company, Inc.

> hydrophobic amino acids, while those with purines in the second position correspond mostly to polar amino acids ...

While by no means comprehensive in definition, the terms mutation above encompass variation which does not change the wild type, and in fact establish that there exists no one "wild-type" sequence. This latter term is in itself somewhat ambiguous as wild type must be operationally defined as a particular enzyme having a particular subset of activity. In the instant case the isolated Δ-12 desaturase gene wild type is not defined by a single sequence, as explained above, and as such the disclosure of Lightner et al. is seen to teach the motif and clearly anticipate the invention. While independent claim 1 has the limitation of "effective for altering the fatty acid composition" it is noted that both functional and non-functional Δ-12 desaturase genes would meet that limitation.

Claims 27, newly amended, is rejected and claims 28-31, 34-35, 38-39 and 42-43[5], remain rejected, are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Browse et al. for the reasons of record as applied to unamended claims 27-31, 34-36, 38-39 and 42-43 as set forth at page 8 of the previous Office Action[6].

Applicants argue that Browse et al. do not describe a mutation in a region encoding a His-Xaa-Xaa-Xaa-His motif in a Δ-15 desaturase and instead state that the desaturase in this publication is that of a wild-type Δ-15 desaturase. Applicants' arguments have been carefully considered and are not deemed persuasive.

Applicants arguments mirror those as applied to the rejection under Lightner et al. and response in that rejection is incorporated herein by reference.

Claims 1, 5 and 35, newly amended, are rejected, and claims 2-4, 8-9, 27-29, 31, 34, 36-39, 42-45 and 55-65 remain rejected under 35 U.S.C § 103 as being unpatentable over Lightner et al. and Browse et al. in view of Pleines et al. for the reasons of record as applied to unamended claims 1-5, 8-15, 18-31, 34-39, 42-45 and 55-65, as set forth at pages 8-9 of the previous Office Action.

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[5] Applicants included claim 36 in their list of claims rejected. Claim 36 was canceled by applicant's amendment.

[6] The HDCGH motif is found in 149955-98-6 as stated in the previous Office Action.

Applicants arguments mirror those presented above as applied to Lightner et al. and Browse et al. and add specific comments to Pleines et al. Pleines et al. is stated to teach the selection of plant lines with reduced $C_{18:3}$ by breeding, and the suggestion that mutagenesis could improve said selection and breeding. Applicants argue that the combination of Pleines et al. with the other references do not suggest the at least one mutation in the claimed motif. Applicants' arguments have been carefully considered and are not deemed persuasive.

The presumption that neither Lightner et al. or Browse et al. teach the claimed motif is not agreed with, for the reasons stated *supra*. What these authors fail to teach is the use of mutagenesis to select variants in fatty synthesis to modify the $C_{18:1}/C_{18:3}$ oil seed ratio, which as evidenced by Pleines was a old and well known technique.

Finally, it is noted that applicants argue that the rejections are a case of hindsight reconstruction. Applicants' arguments have been carefully considered and are not deemed persuasive. A rejection over prior art must, in point of fact, be a type of hindsight reconstruction, as was set forth in the decision *for In re McLaughlin* 443 F.2d 1392, 170 USPQ 209, 212 (CCPA 1971).

The court noted:

> [a]ny judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper.

It is submitted that the rejection only relied on the knowledge which was within the skill in the art and does not use that which may be gleaned from the disclosure as applicant fails to point out what from the disclosure used in the rejection was so taken. The strongest rationale for combining references is a recognition, expressly or implied in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker* , 702 F.2d 989, 217 USPQ 1, 5 - 6 (Fed. Cir. 1983).

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[1] The motif *HRRHHH* was correctly understood by applicant to in fact refer to *HRRHH*.

Summary

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, THIS ACTION IS MADE FINAL. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this or earlier communication from the examiner should be directed to Gary Benzion, Ph.D. whose telephone number is (703) 308-1119. The examiner can normally be reached on Monday-Friday from 8 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas W. Robinson can be reach on (703)-308-4618. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Benzion
07/01/98

GARY BENZION, Ph.D.
PRIMARY EXAMINER
GROUP ART UNIT 1649